

1 gain anything from doing that.

2 DR. FINDER: One issue that I would bring  
3 up is what would happen if some of the physicians are  
4 from multiple facilities and some of the other  
5 physicians don't have data from some of them. It  
6 becomes an inspection type issue that we have to at  
7 least look at to figure out the complexity of that.

8 Who do we end up citing if some data isn't  
9 there?

10 DR. FERGUSON: Well, and the problem I see  
11 and the reason I don't think it should be mandated is  
12 that one facility may have a whole different group of  
13 patients that may be doing primarily diagnostic, and  
14 I'm reading, and the other is doing screening, and  
15 another guy is reading. You combine that data, and  
16 you have a different subset of patients. That's why I  
17 don't think it ought to be mandatory.

18 DR. BARR: And as best as I understand the  
19 recommendation here, at least at this level of audit,  
20 and you'll see as we go along the recommendations are  
21 for different levels of audit, I interpret this to  
22 say, based on D, that we should allow facilities to do

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1 this, but there would be no difference in the  
2 inspection procedure or any citation for facilities  
3 that don't do this.

4 E in Recommendation No. 1 is increase  
5 reimbursement rates to cover new audit procedures.  
6 Rationale is costs are already significant. The new  
7 audit procedures will add to expense. Costs were not  
8 factored in past reimbursements, and health care  
9 payers should cover costs.

10 That probably doesn't require much  
11 discussion.

12 DR. FERGUSON: I definitely support that.

13 (Laughter.)

14 DR. BARR: Recommendation 2, and here you  
15 see --

16 CHAIRPERSON HENDRICKS: I'm sorry to  
17 interrupt. I just wanted to return before you move  
18 into the second set of recommendations because we have  
19 so many talented diagnostic radiologists here on the  
20 panel and also Dr. Barr.

21 If we're not able to accept these three  
22 metrics, for example, to try to establish some quality

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1 parameters in mammography, for you in the trenches who  
2 actually do this, which parameters are useful for  
3 determining quality of care, either a simple or more  
4 complex? What can we offer in lieu of?

5 If we do not accept these recommendations  
6 for the reasons that were stated in the discussion  
7 we've had so far, what is a good surrogate if one  
8 exists?

9 DR. BARR: I do think your question is an  
10 excellent one. I do think it might be helpful if I  
11 run through the next levels of audits and bring out  
12 different parameters, and then perhaps we can discuss  
13 this as a whole on point to your question, which is  
14 very well put.

15 Although this is a different  
16 recommendation, it still relates to audits, and this  
17 is a voluntary advanced medical audit with feedback.  
18 So we sort of see the baseline that we talked about  
19 and then this, and then we can address Dr. Hendricks'  
20 question.

21 In this recommendation of a voluntary  
22 advanced medical audit with feedback, the

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1 recommendations that the audit should include  
2 collection of patient characteristics and tumor  
3 staging from pathology reports. The rationale is to  
4 record more useful data from pathology reports, such  
5 as tumor size and lymph node status, record patient  
6 characteristics, such as age, family history, breast  
7 density, presence of prior films and time since last  
8 mammogram.

9 I'm just going to run all through this and  
10 then we'll go back.

11 Establish a data and statistical  
12 coordinating center to electronically collect, analyze  
13 and report advanced level audit data and provide  
14 regular feedback to interpreting physicians.

15 I think we see here why there were all the  
16 cost recommendations. I don't think it pertains so  
17 much to that initial recommendation, but to some of  
18 these more advanced ones.

19 Develop, implement, and evaluate self-  
20 improvement plans for interpreting physicians who do  
21 not achieve benchmark performance, and aggregate  
22 summary data on interpretive performance, including

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1 recall rates, PPV-2, and cancer detection.

2 Under the same recommendation would be to  
3 test different methods of delivering audit results to  
4 interpretive performance, study randomly selected  
5 facilities using required basic audit procedures for  
6 impact on interpretive quality, protect quality  
7 assurance data from discoverability, and the rationale  
8 for all of this. The statistics and analysis group  
9 needed for uniform feedback to improve quality,  
10 studies needed on feedback to improve performance,  
11 national benchmarks needed for facilities to assess  
12 performance. It would test the impact of basic audit  
13 procedures, and the Breast Cancer Surveillance  
14 Consortium and the Agency for Health Care Research and  
15 Quality should be utilized as they are viable models  
16 for data collection procedures.

17 And, again, the report stresses several  
18 times the discoverability issue.

19 So now back to Dr. Hendricks' question, I  
20 think we could use some input on, you know, what you  
21 think of the ideas in these recommendations, and if  
22 you don't think that these are the things that

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1 necessarily need to be looked at to improve  
2 performance are the things that you do think are  
3 necessary to be looked at and collected to improve  
4 performance.

5 CHAIRPERSON HENDRICKS: We'd also like to  
6 invite comment from the patient advocacy  
7 representatives on the panel, from their perspective.

8 MS. PURA: It's interesting. We're going  
9 through this right now with our primary care  
10 clinicians in attempting to get them to report tumor  
11 size and axillary lymph node status, et cetera, and  
12 this is required by the CDC for payment for our state  
13 program.

14 Just getting the reports are unbelievable.

15 I mean there are various routes one can go, but  
16 surgeons notoriously do not return this information to  
17 primary care clinicians. I can't see how they'll even  
18 return it to a radiology group, more or less our  
19 primary care clinicians who may have some input into  
20 treatment.

21 I don't know where this information would  
22 be very valuable in a radiology audit to see

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1 capabilities of the radiologists themselves in  
2 practice. Hopefully they'll be identifying tumors. I  
3 don't know if they need to get into axillary node and  
4 if they need to get into staging and tumor size, et  
5 cetera. I don't see where that, in fact, has anything  
6 to do with their quality of practice, and obtaining  
7 that information may be very timely and very costly  
8 for them.

9 I'd like to see how everybody else feels  
10 about that.

11 CHAIRPERSON HENDRICKS: Yes, Dr. Lee.  
12 Could you step forward to the microphone, please, and  
13 reintroduce yourself to the group?

14 Thank you.

15 DR. LEE: I'm Dr. Carol Lee. I'm from  
16 Yale University, and I also represent the American  
17 College of Radiology.

18 I respect your comments, but I disagree.  
19 I think it's very important for radiologists to know  
20 the stage of the cancers that we detect because we're  
21 only picking up large cancers that have already  
22 spread. We're not doing a whole lot of good, and the

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1 goal for mammography and one of the indications of  
2 quality is that we do detect small, treatable cancers.

3 So that is very important information. I agree  
4 completely with the difficulty associated with the  
5 collection of that data and also, if I may just make a  
6 comment about what I believe is some useful metrics,  
7 what we want to know is the cancer detection rate, and  
8 we want to know what our false negatives are, and  
9 right now the discoverability of the false negatives  
10 is very difficult.

11 There are no well established, widespread  
12 mammography registries. Tumor registries exist, but  
13 they are hard to access that information, and I think  
14 these are all issues that can be hopefully addressed.

15 MS. PURA: Again, I agree with Dr. Lee in  
16 evaluating size and so on, and it's very important to  
17 know, but finding that information has become a real  
18 difficult problem, and I am very concerned. The  
19 information is absolutely important to the diagnosis,  
20 and the ability of the radiologist, but I am concerned  
21 about them getting that information, and will that,  
22 again, cause the access to radiology to go down

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1 because of another stringent regulation on them.

2 DR. BARR: I think one thing the Institute  
3 of Medicine is trying to get to here is that the way  
4 the audit is now it's fairly basic. You know, you  
5 need to do an audit, and we go in at inspection time,  
6 and ask you if you've done the audit, and that's about  
7 it.

8 Do you think that in regulation there  
9 should be more requirements for what the FDA looks at  
10 as far as what's been done for the audit? And should  
11 that information just stay at the facility? You know,  
12 what should be done with it other than the inspector  
13 seeing that it has been done? Do you think there  
14 should be citations for people who don't do these  
15 things?

16 I think that's what they're trying to get  
17 at, is the audit is pretty basic, right now what FDA  
18 requires, and is there anything else that you think is  
19 vitally useful in that arena.

20 CHAIRPERSON HENDRICKS: That's a good  
21 background. I think the way to think of this is  
22 what's happening across health care. Certainly

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1 hospital based health care in the United States is the  
2 creation of these report cards for hospitals. They  
3 don't like them, but they're certainly out there and  
4 maybe even before their time, but I think we should  
5 think about we know -- we can recognize good quality  
6 mammography facilities and poor ones or maybe ones  
7 which don't have as high quality. So we have to think  
8 about what would be on a report card and how they can  
9 be evaluated without, you know, basically shutting  
10 them down by creating some onerous regulations.

11 But yet we know that we need to be able to  
12 evaluate them and compare them to one another. So  
13 what would be on a mammography report card to identify  
14 an A-plus facility compared to a facility that is  
15 marginal or offering poor quality imaging?

16 Dr. Monticciolo.

17 DR. MONTICCIOLO: I guess I'll just make a  
18 comment. I realize that the auditing right now is  
19 under a lot of scrutiny. It's hard for me as a  
20 practicing mammographer to think that adding these  
21 additional burdens is going to improve interpretation  
22 because I don't see any evidence that ultimate patient

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1 outcomes are affected.

2 I think what we're doing now is we're  
3 trying to look at certain benchmarks in our practices  
4 to see how we compared to each other in a certain  
5 practice setting, and those are somewhat useful, but  
6 the extent of auditing here is going to be  
7 tremendously cumbersome, and I'm not so certain that  
8 it's going to affect the interpretative ability of the  
9 physicians involved.

10 And so I'm not convinced that there's  
11 evidence of that, and that's why I'm not a big fan of  
12 adding more and more layers to how much we collect and  
13 look at. There's only so many hours in the day and  
14 already my colleagues who are not trained in breast  
15 imaging, they usually follow my lead, and so whatever  
16 mistakes I'm making, I guess, are being multiplied,  
17 but you know, usually I'll set the standard, and I've  
18 pushed the standard up for people who are just kind of  
19 doing other things and doing a little bit of  
20 mammography, but you know, I look at this and say,  
21 "Well, if we add more and more layers, I think more  
22 and more people will just drop out."

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1           And the people who want to do a good job,  
2           I think, are personally driven to do that, not that  
3           they shouldn't be looked at, but over scrutinizing  
4           them and collecting more data I don't think is going  
5           to change their interpretation tremendously.

6           And I agree with Linda's comments about  
7           tumor staging. These things are important, but to  
8           acquire that data and to really try to dig this up and  
9           put out reports every year on it is further going to  
10          diminish the desire of people to enter the field.

11          So I'm very concerned about that. So  
12          unless something is really proven to improve the  
13          interpretive ability of physicians, I'm not in favor  
14          of just laying it on and hope that it would help.

15                 CHAIRPERSON HENDRICKS: Yes, Ms. Holland.

16                 MS. HOLLAND: Jackie Holland from Ohio.

17                 I'd like to know if anyone can tell me  
18          what the rationale was in the first place for the FDA  
19          to verify that it had been done but not collected. I  
20          don't understand why they were even verifying it if  
21          nothing was going to happen and if it didn't really  
22          affect the inspection.

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1 DR. FINDER: It's Dr. Finder.

2 The rationale behind it was that this  
3 information which hadn't been required of facilities  
4 in the past was to be used by the facility. In fact,  
5 we do have regulations that talk about the audit  
6 interpreting physician who oversees this process, and  
7 part of their responsibility is to get back to the  
8 individual physicians involved in this audit with  
9 their results and talk it over with them.

10 But we did not in regulation specify what  
11 actions were to be taken or what were the benchmarks  
12 or what analysis was to be done. It was supposed to  
13 be an educational activity for the facility to improve  
14 on their own without getting into the specifics and  
15 telling them how and what they had to do.

16 And the recommendation from IOM is to get  
17 a little bit more specific in terms of what they  
18 should be doing. My understanding at least on the  
19 simple audit, the general audit would be that there  
20 wouldn't be much other change. We wouldn't collect  
21 this data for a national database. It still would  
22 remain within the facility, but it would be more

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1 standardized for them within that facility to look at  
2 their own data.

3 I will tell you some of the arguments that  
4 were brought up at the original time when we were  
5 talking about audits and why we didn't ask for  
6 specifics at that time were that any statistical data  
7 that you might obtain is highly dependent on a number  
8 of factors, including volume, and one of the worries  
9 that was brought up at that point was that you might  
10 have a low volume reader whose numbers could be  
11 bouncing around all over the place, and it wouldn't  
12 mean that there's any real change. It's just the  
13 statistical variation that occurred.

14 Another was the business and discussion of  
15 what constituted screening and diagnostic because the  
16 baseline benchmarks for those two groups are  
17 different. Populations are different. You know, if  
18 you're dealing with one population group versus  
19 another, the incidence of cancer can be significantly  
20 different in those, and trying to compare over the  
21 country certainly would cause problems, although again  
22 by trying to limit it to just a single facility, we

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1 were hoping to kind of minimize that variation because  
2 everybody reading at that facility presumably would be  
3 looking at the same population.

4 So that's the history.

5 DR. BARR: And, Ms. Holland, this is Dr.  
6 Barr.

7 I don't really think that if you don't do  
8 the audit you don't get cited. If there's no evidence  
9 that you can provide to the inspector at all that an  
10 audit takes place, then you can get a citation for  
11 that, but there are no specific elements other than  
12 that it has to be divided up by physician, and we're  
13 asking if you all think there are any other specific  
14 elements that should be in the audit that the  
15 inspector would specifically take a look at to see if  
16 its' there.

17 I don't want you to think you can just  
18 totally not blow it off and not have some consequence.

19 You can get a citation, but other than that, there  
20 are not a lot of specifics in it, and I think that's  
21 what the IOM is trying to get to.

22 DR. FERGUSON: I'd like to say I agree

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1 with the other two panel members that I think this  
2 would be a burden that we don't need, that will not  
3 help the interpretive skills of the physician, which  
4 looking back, that's what they wanted to know. How  
5 can we help with mammography interpretations?

6 And I'll say the audit -- I'm thinking  
7 back when I first started doing my audit is when it  
8 was required, and it has helped me personally to look  
9 at my numbers and to hopefully improve every year and  
10 see what I missed and go back and see what I missed  
11 and why I missed it, and it has helped me improve in  
12 my interpretation.

13 So I think that the audit that we have --  
14 and I was surprised, like she says. Why did we have  
15 an audit and it didn't go anywhere? It has helped me  
16 personally as an interpreting physician. And should  
17 it go any further? I don't know.

18 MS. PURA: Have there been any benchmarks  
19 that have been offered by either ACR or by BIO of IOM  
20 for this particular categories in various staging?  
21 Has anything come out, Dr. Finder, that you know of?

22 DR. FINDER: In terms of benchmarks, there

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1 have been a number of publications that talk about  
2 various benchmarks for screening for diagnostic and  
3 for mixed facilities. Dr. Sickles has done an article  
4 and talked about various benchmarks.

5 Even before MQSA, there was a publication  
6 by the AHCPR, which is now AHRQ; a study done by the  
7 federal government, a nongovernmental agency of the  
8 federal government, whatever that means, published  
9 some benchmark guidelines that can be used by  
10 facilities.

11 So, yes, there is information out there  
12 where you can kind of compare yourself against some  
13 kind of national standard, but it doesn't really take  
14 into account the variation that can occur in an  
15 individual facility, and if a facility wants to look  
16 at that data and compare itself to it, it's truly on  
17 an educational basis, whereas if it was mandated that  
18 there be some benchmark, then that's a whole different  
19 story.

20 But there are numbers that facilities can  
21 look at.

22 DR. BARR: Okay. So I think in summary

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1 what I'm hearing then is that we should continue at  
2 inspection to look that an audit has been done, that  
3 it should be by individual physician, but that we  
4 should allow facilities who can and want to to combine  
5 audit data across centers to look at larger numbers.

6 That's what I'm hearing so far, and we'll  
7 go on to the -- there's a little more in this advanced  
8 audit piece.

9 Recommendation 3 is to designate  
10 specialized breast imaging centers of excellence. The  
11 first part under that in the report is that these  
12 centers will participate in basic and advanced medical  
13 audits and test approaches to improve quality and  
14 effectiveness. They would test effects of high  
15 volume, double reading, quality assurance, patient  
16 reminders. They would develop and evaluate  
17 interpretive skills assessment exams.

18 The rationale behind these recommendations  
19 was stated that several countries have integrated  
20 centralized breast cancer screening programs, but in  
21 the U.S. screening is decentralized and offered in  
22 diverse practice settings.

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1           These excellence centers could provide  
2 multi-disciplinary training and work environments for  
3 diagnosis, could increase job satisfaction, retention  
4 of practitioners' productivity, and quality of the  
5 breast care team.

6           High quality facilities could attract high  
7 quality personnel. Incentives for becoming one of  
8 these centers of excellence would be similar to what  
9 was stated previously: high reimbursement rates, and  
10 could be used to recruit patients and referrals. I  
11 guess you would be allowed to put out that you're one  
12 of these centers of excellence.

13           Rationale that supportive elements and  
14 incentives are critical to encouraging facilities and  
15 personnel to strive for higher quality. These centers  
16 should serve as training centers for breast imaging  
17 and regional mammogram readers. The centers would  
18 have the expertise to develop and host training  
19 programs in imaging.

20           Interpretation at centralized facilities  
21 could help alleviate access in low volume areas. The  
22 centers should be linked with facilities that provide

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1 comprehensive and multi-disciplinary breast care. The  
2 rationale is that imaging based centers need  
3 continuity with facilities providing non-imaging  
4 breast care treatment and follow-up.

5 And so any comments on these breast  
6 imaging centers of excellence?

7 CHAIRPERSON HENDRICKS: I'll start out  
8 with a comment. I just wonder, Dr. Barr, in your  
9 opinion and with your familiarity of mammography  
10 facilities in the United States, which centers do you  
11 think are already meeting these criteria, if any, or  
12 how many?

13 DR. BARR: Well, I think that gets back to  
14 like a score card like you said or a report card of  
15 facilities, and you know, various states have tried to  
16 market facilities as being, you know, in the upper  
17 echelon or in different strata and, you know, have  
18 found huge problems with doing that.

19 The best that I can tell you from our data  
20 is that 70 percent of the mammography facilities in  
21 the country practice quality mammography as defined by  
22 MQSA, and you know, that's the best I can tell you

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1 right now.

2 DR. MARTIN: Dr. Hendricks.

3 CHAIRPERSON HENDRICKS: Yes.

4 DR. MARTIN: Melissa Martin.

5 As a consulting physicist, I see what I've  
6 usually referred to as the good, the really good, and  
7 then the ones that barely meet the criteria, and I  
8 would just highly encourage us to or encourage the FDA  
9 to pursue this idea because there is definitely a vast  
10 difference in the quality of care out there, and I  
11 think we do need to encourage this development and  
12 designation for those centers that are doing upper  
13 level quality care.

14 And if you ask me, I would say, well, we  
15 currently cover around 300 facilities, and I would say  
16 probably 100 of them definitely meet it already, but  
17 they are definitely doing more, personnel-wise, skill-  
18 wise, education-wise, than the local stand alone unit  
19 that does screening only, and I think we need to  
20 differentiate what those facilities are doing.

21 DR. BARR: And, Ms. Martin, would you put  
22 that information out publicly and for patients that

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1 didn't have access to such a facility, what would you  
2 tell them?

3 DR. MARTIN: To encourage them to get  
4 access to that level facility.

5 DR. BARR: Even though such a facility  
6 that you're describing might not be available to them.

7 DR. MARTIN: Well, I function in a very  
8 crowded area, and I find it very frustrating sometimes  
9 that we have the equivalent of a center for  
10 excellence, and three blocks down the road we have a  
11 minimally qualified facility that is still in practice  
12 and getting paid the same as the facility that's a  
13 center for excellence.

14 DR. BARR: And at one time we say under  
15 MQSA, you know, we're talking about standards across  
16 the board so that any facility who meets them, you  
17 know, meets the criteria.

18 CHAIRPERSON HENDRICKS: Another question  
19 might be if we propose to the mammography centers of  
20 the United States whether they wanted that  
21 designation, how many would voluntarily want to  
22 undergo the steps that it would take. What is your

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1 feeling on that?

2 Because we've heard that the current  
3 basic, you know, bare minimum audit is burdensome. So  
4 do you see that there would ever be any desire for  
5 even the excellence centers to get this designation?

6 DR. BARR: You know, I think a lot of it  
7 depends on what a lot of people have already said in  
8 how much money would be available to centers, how the  
9 reimbursement would be affected by, you know, if you  
10 could receive higher reimbursement for doing this, if  
11 Congress is going to give money for doing this.

12 But like a lot of things, I think people  
13 might be loath to do these requirements because they  
14 don't have the money or the manpower to do it.

15 I also worry about, you know, the woman in  
16 rural North Dakota who doesn't have access to what  
17 people -- I don't even think we have the criteria for  
18 what one of these centers of excellence is, but I also  
19 worry what we tell the people who, you know, don't  
20 have -- if facilities become these centers of  
21 excellence, how do you get access to them?

22 You know, perhaps as the digital age gets

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1 more advanced, that problem might be decreased, but  
2 right now I do worry about what we would tell patients  
3 who would say, "Well, does that mean the center I go  
4 to isn't good enough?"

5 You know, MQSA, there's a certificate on  
6 the wall. My center has had no violations that I'm  
7 aware of. You know, does that mean I'm not getting  
8 good care, that I've got to get on a plane and fly  
9 somewhere to go to one of these centers of excellence?

10 CHAIRPERSON HENDRICKS: Yes.

11 DR. WILLIAMS: This is Dr. Williams.

12 With respect to the question of being able  
13 to afford establishing centers of excellence, I know  
14 that many academic institutions have lots of centers  
15 of excellence, cardiac centers of excellence,  
16 digestive centers of excellence, and many of these  
17 programs have been to a certain degree underwritten by  
18 grants from the NIH.

19 And one of the things that would be worth  
20 considering is whether some of the funding, whether  
21 it's NCI or someone else, would be interested in  
22 putting out specifically RFAs for establishing these

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1 centers and with perhaps the express statement that  
2 there would be funding written into the budgets for  
3 assisting access to these centers for women who are  
4 not located necessarily right next to them.

5 DR. BARR: Yeah, I think that's an  
6 excellent comment. Thank you.

7 One thing I'd just like to point out is as  
8 far as I know most of those other kind of centers of  
9 excellence, you're not talking about a screening  
10 modality, and I think that that, you know, plays a  
11 role here.

12 Yes, Dr. Ferguson.

13 DR. FERGUSON: I agree that a designation  
14 of a center of excellence will cause burdens in more  
15 rural areas like mine. Women will say, "Well, I have  
16 to seek this facility," and facilities who are doing  
17 good quality work will dry up and you will lose  
18 access.

19 Like Dr. Williams says, I think incentives  
20 are an excellent idea for people to try to attain  
21 this, and the incentives in the form of grants or  
22 increased reimbursement for facilities who meet these

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1 criteria are excellent ideas, but to go out and  
2 designate them, still continue to pay everybody the  
3 same and say one is better because they provide  
4 training and multi-specialty facilities, I think,  
5 would ultimately harm access to quality care that is  
6 out there.

7 CHAIRPERSON HENDRICKS: If I could  
8 interject before we go to Linda who had a comment, a  
9 lot of the members of this panel don't have to deal  
10 with payers, but the way that the big payers in this  
11 community are headed, I think as this whole idea of  
12 pay for performance.

13 I think every big insurance carrier in the  
14 United States is very much interested in reimbursement  
15 and lowering reimbursements for some services, but  
16 increasing reimbursements for what they're certain is  
17 high quality medical performance. So that's a little  
18 bit of a circular argument because if we go to the  
19 payers to ask for support and increase reimbursement  
20 for a breast center of excellence or even a center  
21 that has met all of the criteria for our audit, we  
22 have to go to them with some metric to demonstrate

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1 that, in fact, we should be paid for excellent  
2 performance.

3 Linda, you had a comment?

4 MS. PURA: There's pros and cons, of  
5 course, for the centers of excellence, but in the  
6 milieu that I live in and work in, the women that we  
7 see, if we can have and be so blunt to say a one shop  
8 stop that has many, many procedures that are offered  
9 and women don't have to come back, that eases some of  
10 the access to going to various and sundry places to  
11 get the procedures that they need.

12 I would, of course, want to see that a  
13 center of excellence does take the Medicaid patients.

14 That's another major problem that we are finding now,  
15 is that centers are refusing to take, as I say, our  
16 women, and so that would be, if I was looking at a  
17 facility, that would be something that I would want to  
18 see.

19 However, I don't know if we have any  
20 impact on the federal reimbursement for Medicaid at  
21 all.

22 CHAIRPERSON HENDRICKS: We have time maybe

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1 for one more brief comment on this topic before you  
2 break for lunch.

3 DR. BARR: That sounds good. I'd like to  
4 point out here that I think one thing that IOM is  
5 saying in these centers of excellence is, you know,  
6 not only would it be a designation that patients could  
7 use, but that these centers would be the ones that  
8 would test out the different things that are now on  
9 the table that might improve quality: the high  
10 volume, the double reading, different things like  
11 that; that these centers would sort of be our  
12 researchers, as it were, into what things might  
13 improve quality.

14 CHAIRPERSON HENDRICKS: Yes, from the  
15 audience, the final comment before lunch. Please  
16 introduce yourself.

17 DR. SHOPE: Yes. I'm Tom Shope. I'm with  
18 the CDRH.

19 I'm not directly involved in the  
20 mammography program in great detail, but it seems to  
21 me like it's worthwhile making one comment here, and  
22 that is the discussion of this Institute of Medicine

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1 report is the report was made to Congress. It was a  
2 report about the national mammography situation and  
3 what Congress ought to do in order to improve  
4 mammography, and so it's not a directive to FDA to do  
5 all of these things.

6 And so I just wanted to say when it talked  
7 about a voluntary additional medical audit kind of  
8 thing, the first word there was voluntary. I mean,  
9 that seems to have gotten lost in the conversation  
10 here, that they were suggesting there be some  
11 mechanism set up to perhaps provide some  
12 recommendations as to what a good quality audit might  
13 look like in a facility and some way to encourage  
14 facilities to implement these things.

15 I don't think there was any requirement  
16 that FDA make this mandatory, and the same thing here  
17 with the imaging centers of excellence. It sounds to  
18 me like a recommendation to Congress from the IOM that  
19 Congress consider how could we foster the  
20 establishment of these kinds of -- and I see them as  
21 research facilities -- to look at the effects of the  
22 various things that one might do to improve

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1 mammography, not necessarily that FDA would require  
2 all of the facilities to do these things or that we  
3 would set up criteria for when you qualify to be one.

4 I think what Congress was doing is saying  
5 we need to have some ways to encourage the  
6 establishment of these things. The IOM was saying to  
7 Congress that which might, of course, get into the  
8 issue of who would fund them, how would they be  
9 established, all the research activities that need to  
10 go on.

11 So I don't think it was a message that FDA  
12 necessarily needed to do. Pardon my butting in, but I  
13 think it seemed like there was something he had missed  
14 here.

15 CHAIRPERSON HENDRICKS: I appreciate that  
16 comment.

17 And with that, I think we'll take a break,  
18 and then, of course, we'll be resuming this same  
19 discussion and working our way through the document  
20 after a one hour lunch break.

21 We'll return then in one hour and 15  
22 minutes. We'll reconvene at one o'clock.

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1 (Whereupon, at 11:47 a.m., the meeting was  
2 recessed for lunch, to reconvene at 1:00 p.m., the  
3 same day.)  
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AFTERNOON SESSION

(1:04 p.m.)

CHAIRPERSON HENDRICKS: I want to call to order the afternoon session.

We're going to resume the discussion that we held this morning with Dr. Helen Barr helping guide us through a discussion of the Institute of Medicine recommendation beginning with Recommendation No. 4.

DR. BARR: Thank you and welcome back.

Before I go on to Recommendation No. 4, I just wanted to make a very brief comment about Dr. Shope's comment from the audience which we ended with when we broke, and you know, he's perfectly correct. This is a recommendation to Congress. I was actually going to talk about that a little bit later when it becomes abundantly clear that it's not FDA; that it would take, you know, a multitude of HHS and other agencies and other venues to institute some of these things if they were to be.

However, with that being said, Congress will definitely be looking to FDA, especially on the regulation part. You know, I think the biggest

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1 danger we all feel is that Congress will expect these  
2 things to be done without appropriate monies,  
3 incentives, et cetera, along with it.

4 Recommendation No. 4 under the section  
5 we've been working on is to study the effectiveness of  
6 continuing medical education, reader volume, double  
7 reading, and computer aided detection.

8 First, the recommendation is to  
9 demonstrate the value of CME for improving  
10 interpretive skills. The report cites the rationale  
11 as this would enable interpreting physicians to  
12 identify weaknesses and take steps to improve  
13 interpretive performance. We could continue to  
14 develop innovative teaching interventions to improve  
15 interpretive skills.

16 Anybody want to make any comment on  
17 demonstrating the value of CME for improving  
18 interpretive skills?

19 I think this is particularly important  
20 because at the time of the last reauthorization we  
21 almost had in the reauthorization, but didn't get a  
22 proposal that was on the table to make five of the 15

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1 CMES for physicians that we currently require into  
2 self-assessment type CMES.

3 And I think it didn't go on the table  
4 because people raised the question that we didn't  
5 really know the value of CME in improving mammography  
6 interpretation. So I think this is an important area  
7 for comment.

8 DR. MONTICCIOLO: Can I make a comment?

9 I just wanted to point out that I think it  
10 is an important area, and I don't know that we'll need  
11 to address it because the American College of  
12 Radiology and the American Board of Radiology are  
13 heading toward the maintenance of certification to  
14 allow people to keep their licenses, and part of that  
15 will be a requirement to have self-assessment modules.

16 So we'll have to have two every year over the ten  
17 years of practice.

18 So already that's going to be mandated to  
19 keep your radiology license. I think that will be  
20 taken care of with that.

21 It's not directed specifically at  
22 mammography.

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1 DR. BARR: Do you mean for your board  
2 certification?

3 DR. MONTICCIOLO: That's correct.

4 DR. BARR: Yeah.

5 DR. MONTICCIOLO: And so I think even if  
6 people that have unlimited certificates will probably  
7 end up adhering to that program just because of  
8 reimbursements, et cetera.

9 DR. FINDER: This is Dr. Finder.

10 I want to bring up that point later  
11 because we actually have a discussion point in our  
12 guidance that we're going to try and discuss this  
13 issue about expiring board certificates. So that is  
14 an important issue that we will hopefully not forget  
15 about later.

16 DR. BARR: Thank you.

17 The next recommendation is to determine  
18 the effects of reader volume on interpretive accuracy,  
19 the rationale being currently there's insufficient  
20 evidence to recommend an increase in minimum  
21 interpretive volume. No basis for specifying a higher  
22 level of reader volume, and again, I think an

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1 important area to comment on, particularly when our  
2 charge is to put things into effect that wouldn't  
3 affect access.

4 So we appreciate your input.

5 DR. FERGUSON: I would agree that I think  
6 the number is sufficient at this time in order to  
7 insure access. There are physicians who don't read as  
8 many as others, that do a very good job, and you know,  
9 400 and whatever it is a year I think is sufficient.

10 DR. BARR: Recommendation C is to look at  
11 the impact of double reading in CAD on interpretive  
12 performance over time in different practice settings  
13 and at different levels of experience.

14 Rationale here is cited as a second look  
15 by another reader or computer program not verified by  
16 prospective clinical trials, and effects on  
17 specificity are not fully understood.

18 CAD programs are being refined. So  
19 effective use could change over time. Studies use --  
20 and I guess give us studies needed on effectiveness  
21 findings could help us use the information more  
22 effectively. Studies need to confirm, if consensus,

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1 double reading may be most effective.

2 Here we go again.

3 CHAIRPERSON HENDRICKS: Comments from the  
4 audience?

5 DR. BARR: In other words, I think that  
6 IOM is suggesting that there's important things that  
7 may go into interpretation, but we don't have enough  
8 information yet.

9 CHAIRPERSON HENDRICKS: We have a comment  
10 from an audience member. Please identify yourself.

11 MS. WILCOX: Pam Wilcox, ACR.

12 These recommendations for studies seem  
13 very important to impacting ongoing quality and  
14 knowing what tools we need, but there doesn't seem to  
15 be any way of addressing the funding for these studies  
16 or where they're going to come from in the IOM report.

17 Has FDA had an opportunity to think about  
18 that or look for opportunities for funding for any of  
19 this, or is that what you're seeking from your  
20 committee?

21 DR. BARR: As we mentioned before, you  
22 know, these are recommendations to Congress, and

1 hopefully Congress will be addressing where funding  
2 for these types of things would come from.

3 MS. WILCOX: So are you sort of seeking  
4 input from this community to point which ones you  
5 really want to push to Congress to get funded for  
6 studies?

7 DR. BARR: Yeah, I think we're seeking  
8 input of which of these things, you know, do we think  
9 might affect interpretive skills, if any, and are they  
10 worth studying. Do we have enough information now on  
11 any of them to require them? You know, do we need to  
12 study them?

13 I think the funding questions are  
14 obviously right up there on everybody's mind.

15 Thanks, Pam.

16 Anybody have any comments on the funding  
17 issues or if any of these are worth studying? I mean,  
18 it certainly seems that before we get something in  
19 regulation, it's my understanding from people that we  
20 would like to have data that shows that any  
21 regulations that we get are worthwhile having and are  
22 on point to the task at hand of improving

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1 interpretative skills.

2 MS. MOUNT: Carol Mount.

3 From what we have evaluated at our  
4 institution, I think that the CAD program would be  
5 something that would be definitely worth pursuing. We  
6 have run our own study and found that it did increase  
7 the early detection rate by having the CAD.

8 DR. BARR: Thank you. That's good  
9 information to know.

10 If anybody else has experience with CAD  
11 that they'd like to share.

12 Charlie, do you have any?

13 DR. FINDER: Dr. Finder.

14 I just wanted to point out a couple of  
15 things in terms of the past history. It's interesting  
16 to note that as Dr. Barr mentioned earlier, some of  
17 these items that IOM looked at were issues that were  
18 brought before earlier versions of this committee in  
19 terms of possibly implementing these as regulation,  
20 the idea of making some of the CME and interpretive  
21 skills type CME. Raising the number of mammograms  
22 read over a period of time has certainly come up many

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1 times. The issue of double reading has been discussed  
2 many times, and certainly CAD is one of those, and  
3 it's just interesting that the IOM when looking upon  
4 this didn't feel that there was enough evidence at  
5 this point to actually make any recommendations to FDA  
6 to actually implement any of these things.

7 My question to the people here is: what  
8 type of evidence do you think would be useful for  
9 somebody in the future to decide whether these were  
10 actually useful things to implement or not? Does  
11 anybody have any idea of what type of research, what  
12 type of study could be done, not necessarily that FDA  
13 would do it? As has been pointed out, this is an  
14 issue that Congress is going to hopefully eventually  
15 decide will be looked at by somebody, but not  
16 necessarily FDA.

17 DR. WILLIAMS: This is Dr. Williams.

18 On the topic of CAD, I think probably  
19 quite a number of groups would agree that that's  
20 something that kind of needs to be looked into and is  
21 being looked into, and it shows a lot of promise.

22 I think there has on the topic of funding,

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1 there have been a number through the years of very  
2 well funded basic studies on the effect of CAD, and  
3 what it sounds like we're talking about now is a  
4 fairly large multi-center trial that would evaluate  
5 the effectiveness of CAD across a variety of different  
6 types of institutions, and the thing that springs to  
7 my mind there as one possibility would be Akron.

8 Akron, as you know, one of its charters is  
9 to evaluate the early efficacy of diagnostic tools,  
10 and now having the DMIST trial just wrapped up or not  
11 wrapped up, but the first results now out, that might  
12 be a reasonable thing to think of for the future.

13 DR. BARR: Thank you.

14 I think those are on-point comments, and I  
15 think these things are also going to lead into people  
16 now, for example, CDC and its breast and cervical  
17 cancer program, you know, paying for CAD or continuing  
18 to pay for CAD or increasing paying for CAD, you know,  
19 paying for digital mammography in their program.

20 So a lot of these things are, I think,  
21 important issues. Okay. So I guess what I'm  
22 basically hearing on this part is that we don't have

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1 anything specific. No one is coming forward and  
2 saying, yes, X, Y and Z are the things that we know  
3 improve a radiologist's interpretation, but rather  
4 there are a number of areas such as reader volume and  
5 computer aided detection that we need to continue to  
6 study.

7 I think the Chair can recognize a speaker  
8 from the audience. Before we get too far from audit,  
9 I had someone approach me who might be able to shed  
10 some more light on audits and mammography situations.

11 So if the Chair might recognize, welcome and  
12 introduce yourself.

13 MS. MYERS: Hi. My name is Susanne Myers,  
14 and I'm the Senior Vice President of Mammologics. We  
15 have been in business for about ten years now, and we  
16 assist mammography facilities with auditing, patient  
17 tracking, the notification letters, and the reminder  
18 letters, and I really just wanted to mention one of  
19 the things that we do in the auditing process, and  
20 this goes back to the discussion about screening  
21 versus diagnostic, which is really asymptomatic versus  
22 symptomatic, is we feel it's very important to make

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1 that distinction because in order for you to really  
2 understand your practice and really understand the  
3 audit data, you have to know the mix of your patients,  
4 and that will assist you down the line, and when  
5 you're looking at your data to kind of get an idea of  
6 what the numbers mean.

7 We currently have about four million  
8 breast imaging procedures in our database and we've  
9 been assisting mammography facilities with compliance  
10 issues. One of the things that I just want to point  
11 out is that a lot of mammography facilities really  
12 want to do a better job, but I think there's a lack of  
13 information out there for them to do a better job, and  
14 I think from a guidance standpoint, I think we could  
15 really help with coming out with some guidelines as  
16 far as the auditing requirements. I think we could  
17 really make a difference in the quality of the  
18 mammography services that we are rendering at this  
19 time.

20 And that's really all I wanted to say.

21 DR. BARR: I thought one thing that you  
22 said to me was interesting, that you have facilities

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1 that do 1,800 mammograms. You have facilities that do  
2 18,000 mammograms, but yet you can, you feel, provide  
3 them with significant audit data that can be used in  
4 ways.

5 MS. MYERS: One of the things that we kind  
6 of help our clients with is to look at their data over  
7 time, and a lot of our clients that really are  
8 interested in doing a better job, they have  
9 implemented quality improvement programs when they  
10 actually use the data on an ongoing basis to monitor  
11 what's going on in their practice.

12 So when you're looking at desirable goals,  
13 and that came up before as well, is there desirable  
14 goals that facilities should be striving for, and  
15 obviously it depends. It depends on your patient mix.

16 It depends on how many radiologists you have, how  
17 many facilities that you're servicing. So all of  
18 these things need to be taken into consideration.

19 DR. BARR: Thank you. Appreciate the  
20 comments.

21 MS. MYERS: You're welcome.

22 DR. MARTIN: Dr. Barr, I know several of

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1 us -- I get involved with several facilities when they  
2 say "help with the audit," and I think one of the  
3 frustrations on the facilities end of things has been  
4 as you have said. At this point the audit has been  
5 very wide open. As long as they, quote, performed an  
6 audit, it wasn't really specified what was in it, and  
7 I do think that would be a recommendation if some form  
8 were at least a minimum of what information was  
9 required for the facilities to have in their audit,  
10 but again, I think we need to figure out how we're  
11 going to specify, if at all, what we do with the data  
12 when we get it, and that's what the radiologists on  
13 the panel, I think, have been saying.

14           Benchmarks are going to be totally  
15 dependent obviously on the patient population that you  
16 work with, and at least the feedback I'm getting from  
17 most of the facilities is they're very antsy about  
18 having that number, the magic number set unless we  
19 have very clear standards and databases to go with,  
20 and frankly, obviously, that's not the physicist role.

21       So we're not a lot of input just because of the math,  
22 and sometimes the facilities want help with it.

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1 (Laughter.)

2 DR. MARTIN: So I'm looking for input, and  
3 anything that you can help us establish those  
4 standards or as the committee establishes those  
5 standards, it would be welcome information, I think,  
6 to most of the facilities if someone decides what is a  
7 minimum set of criteria that they have to have ready  
8 for an inspector.

9 DR. BARR: Thank you, and certainly, you  
10 know, we brought that up for discussion, and I  
11 directly asked, you know, what should be in the  
12 audit, what should the inspectors look at, and the  
13 only thing that I heard that there seemed to be a  
14 general consensus on was to allow combining of  
15 facilities' information to look at larger aggregate  
16 data.

17 Thank you.

18 Okay. Now a huge section that we're going  
19 to be dealing with and it's, again, a lot of  
20 information, and this one is going to be particularly  
21 tricky because we're going to be dealing with  
22 recommendations for added wording to the regulations,

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1 deleted wording from the regulations. So see if we  
2 can work our way through this.

3 The next section of the four big  
4 recommendations that I talked about at the beginning  
5 that IOM made falls into the section of revising MQSA  
6 regulations, inspection procedures, and enforcement.

7 Our Recommendations 5 and 6 that fall  
8 under this category is to modify the regulations to  
9 clarify intent and to address current technology; to  
10 modify inspections by streamlining processes, reducing  
11 redundancy, and addressing current technology; and to  
12 strengthen enforcement for patient protection.

13 So we'll start with the Recommendation No.  
14 5, modify regulations to clarify intent and address  
15 the current technology.

16 What IOM recommends in general are the  
17 following, and then we'll be marching through specific  
18 regulations. I want us to remove the exemption for  
19 stereotactic breast biopsy procedures and develop  
20 regulations, and I believe -- correct me if I'm wrong,  
21 Dr. Finder -- that tomorrow we're going to have a more  
22 specific and dedicated conversation on this. So

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1 probably just generally skip over this particular  
2 point today because we have some speakers also on this  
3 issue for tomorrow.

4 To develop regulations for digital  
5 mammography; to update assessment categories to  
6 reflect BI-RADS, including the known biopsy proven  
7 malignancy; to establish luminance standards for  
8 viewing mammograms; to eliminate modality specific  
9 CME.

10 As we march through this specific  
11 regulatory text, IOM's recommendation to added text to  
12 the regulations will be in these kind of parentheses  
13 and green print, and their recommendations to delete  
14 text from the regulations will be the parens that look  
15 like greater and less than, and in the kind of peachy-  
16 orangy print.

17 As I said, we'll skip over the  
18 stereotactic discussion until tomorrow.

19 Develop regulations for digital  
20 mammography. Should develop a uniform set of quality  
21 control tests and test criteria. This should not  
22 preclude performance of additional tests recommended

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1 by the equipment manufacturer, and to update  
2 assessment categories to reflect BI-RADS.

3 So this is our Section 900.12 in the regs.

4 The overall final assessment of findings classified  
5 in one of the following categories, and you see the --

6 DR. FINDER: Dr. Barr.

7 DR. BARR: Yes.

8 DR. FINDER: Can we go back?

9 DR. BARR: Sure.

10 DR. FINDER: On the develop regulations  
11 for digital and just start on that one.

12 DR. BARR: Oh, I'm sorry. Yeah. I didn't  
13 realize we didn't have anything specific read comments  
14 on that because we don't have any.

15 Yeah, Charlie. Could you go into where we  
16 stand now on the --

17 DR. FINDER: Right. Let me try and give a  
18 little bit of the history behind the current  
19 regulations, how we got here.

20 Basically, the regulations were developed  
21 before full field digital mammography, any of the  
22 units were actually approved for commercial use. So

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1 in order to address something that we really didn't  
2 know what was going to happen, we put in a regulation  
3 that said that when these new mammographic modalities  
4 come into existence, facilities would be required to  
5 follow the manufacturer's recommended quality control,  
6 and that's where it stood in 1997 through '99 when the  
7 regs. went into effect, and the first unit, I believe,  
8 was approved in 2000, early 2000.

9 Since that time facilities that have been  
10 using approved digital units have been following the  
11 manufacturer's QC manuals. Each manufacturer, because  
12 of their different technologies, has a slightly  
13 different or sometimes not only slightly, but more  
14 than slightly different quality control set of  
15 procedures.

16 And I think what IOM was suggesting is  
17 that a uniform set of quality control procedures be  
18 developed, and that they be implemented through  
19 regulation once they are, and I know that various  
20 groups are working on developing a unified quality  
21 control procedure. The American College of Radiology,  
22 amongst them, has been working to develop this. I

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1 believe that there may be some information from the  
2 Akron trial, the DMIST trial that could be a benefit  
3 in the future, and I think that the goal of trying to  
4 standardize these processes is one that FDA is  
5 certainly looking forward to. It would make  
6 everybody's life easier if it was one set of  
7 procedures that the facility, the inspector, the  
8 medical physicist would follow.

9 So I guess part of the issue that this  
10 committee can discuss is some of the difficulties and  
11 the different technologies that are involved, and if  
12 anybody has any idea now what we might do to encourage  
13 a development of a uniform quality control set of  
14 procedures.

15 And I look toward the physicists  
16 specifically because they're good at math.

17 (Laughter.)

18 DR. WILLIAMS: Yeah, this is Mark  
19 Williams.

20 Well, first of all, I agree 100 percent  
21 that things may be a little bit different now than  
22 they were in the days when full field systems first

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1 arrived. We have more data. The DMIST trial was  
2 certainly a good source of data because most of the  
3 major FFDM manufacturers were involved in that trial.

4 There were systems from one of them.

5 So we have data for a large number of  
6 different types.

7 Having said that, I think the point that  
8 Dr. Finder raised right at the end is also relevant,  
9 which is that we'll have to be careful when we set up  
10 these unified guidelines to take into account the fact  
11 that of the five different FFDM manufacturers  
12 involved, there were five very different technologies  
13 involved.

14 Now, there have been several papers that  
15 have been published recently that actually did sort of  
16 a systematic analysis that compared the quality  
17 control guidance that right now, as Dr. Finder said,  
18 is really the MQSA regulations, follow what the  
19 manufacturer says. And those papers unanimously  
20 demonstrated that right now there is a huge disparity  
21 in not only the details of the tests that are  
22 recommended, but also in the actual types of tests

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1 that are recommended, with in some cases very few  
2 detector specific tests, and in many cases the tests  
3 that are being recommended, and this is a very logical  
4 and understandable thing, are modeled very closely  
5 after the existing guidelines for screen film.

6 So I think that with that in mind, there's  
7 certainly a clear call for some sort of a unified  
8 approach to quality control for FFDM. I think we have  
9 now, well, we're in the process of getting some solid  
10 data to establish what tests are relevant and what  
11 aren't, and I think the DMIST trial actually  
12 identified several tests that probably are not as  
13 relevant as they might be and, therefore, could be  
14 dropped to simplify the FFDM quality control  
15 procedures.

16 And so I guess in my opinion there's  
17 clearly a very strong motivation to do this, and I  
18 think that there's no doubt that this is the time to  
19 push forward on it.

20 CHAIRPERSON HENDRICKS: A comment from the  
21 audience? Please identify yourself.

22 MS. BUTLER: Hi. I'm Priscilla Butler

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1 with the American College of Radiology.

2 One of the things Mark had been referring  
3 to is an ongoing project at ACR to develop a quality  
4 control manual for full field digital. This is under  
5 the chairmanship of Martin Yaffe in Toronto, who's not  
6 subject to the MQSA regulations right now, but there  
7 are a lot of people on the committee who are.

8 One of the things that I think from the  
9 DMIST trial we've learned a lot of information about  
10 quality control. The DMIST trial was a research  
11 study. All of the facilities were very tightly  
12 controlled in terms of the QC that was done there and  
13 the attention that was paid to the performance of the  
14 equipment.

15 Martin and his group has taken it one step  
16 further to try to come up with a system that is going  
17 to be applicable not only to research sites, but also  
18 to university, to small community centers that maybe  
19 begin doing teleradiology.

20 So currently we have the technologist  
21 section of the manual in a semi-draft form. It's  
22 going through as we speak pilot testing, right, Mark?

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1 DR. WILLIAMS: Right.

2 MS. BUTLER: Right. Okay. And we hope to  
3 make some changes to it from the feedback that we get.  
4 So that's where we are right now.

5 Oh, yeah, and once we come out with  
6 something, we're going to have to come to this group  
7 for an alternative standard to see if it can be  
8 implemented under the regs.

9 PARTICIPANT: (Speaking from an unmiked  
10 location.)

11 MS. BUTLER: It is in draft form, and we  
12 are going to be pilot testing it.

13 DR. BARR: Thank you.

14 So do we wait for that kind of thing to  
15 come out or, Dr. Williams, as you indicate, is there  
16 enough information right now to write specific  
17 regulations related to digital?

18 Also, I would like to add in this I think  
19 that one thing we've learned from our experience with  
20 MQSA is that equipment is, anymore in this day and  
21 age, is really not where the problems in mammography  
22 lie, and we wrote a whole bunch of equipment

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1 regulations.

2 And is that how we also want to go with  
3 digital or do we want to learn from our experience  
4 that equipment is probably not where most of the  
5 issues lie?

6 DR. WILLIAMS: Well, I think that to  
7 answer your first comment, I think that we're probably  
8 not in a position at this moment in time to say these  
9 should be the regulations for FFDM. I think we're  
10 getting there, and I think that once we do some actual  
11 in the clinic evaluation of these draft protocols that  
12 Penny mentioned, we'll have a lot better idea.

13 Because they were called to a large degree  
14 from a kind of a super set of the procedures suggested  
15 by the manufacturers. That's sort of how DMIST was  
16 put together. Everything that was really possible was  
17 really done.

18 And so part of the process that's going on  
19 right now is identifying the minimum useful set, if  
20 you will. We don't want this to be a big and  
21 burdensome set of QC procedures simply because it's  
22 going to be applied across the boards.

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1           So I think that probably we should let the  
2   ACR subcommittee do a little bit more work.   That  
3   would be, I think, well worth the wait.

4           DR. BARR:   Thank you.

5           MS. MOUNT:   Carol Mount.   I'm just hoping  
6   that when these regulations are written, it is taken  
7   into consideration the down time for the room to  
8   perform the procedure.   Currently we have one digital  
9   unit and 11 film screen units in our institution, and  
10   the digital unit requires so much more down time to do  
11   the QC on than the other rooms, and that's time  
12   they're not doing a patient.

13          DR. BARR:   Thank you.

14          DR. MARTIN:   Melissa Martin.

15                I would just reiterate what Mark Williams  
16   has been saying and Penny.   The ACR group has put a  
17   lot of work into this already as far as trying to  
18   develop a cohesive set of requirements that we would  
19   recommend at that point to be included particularly  
20   for the physicist test and the technologist test.

21                I hesitate to have the FDA start or  
22   recommend that you start developing a different set at

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1 this point. I really would encourage us to wait until  
2 the ACR program gets out because that's the group  
3 that's been working on this, and the accreditation  
4 program is fairly advanced at this point rather than  
5 starting another set of criteria.

6 DR. BARR: Thank you.

7 DR. WILLIAMS: Just to comment on the  
8 issue of the down time for the digital rooms, that's  
9 probably true at the moment, and part of that has to  
10 do with the, I guess, unwieldiness of what it is we're  
11 all trying to do when we're in there doing these  
12 tests.

13 One of the things that, of course, we all  
14 hope is going to be a benefit of digital, in addition  
15 to its clinical value, is being able to computerize  
16 many of the things that right now are done in maybe  
17 not the most efficient way, and that might be another  
18 virtue of a standardized set of tests, is that if  
19 these things could be essentially incorporated up  
20 front into the FFDM systems, then it may actually  
21 decrease the down time because there would be a well  
22 established set of analysis, routines, for example,

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1 for doing the test, and we wouldn't be shuffling the  
2 images back and forth from one place to another and  
3 getting them off and doing off-line evaluations and so  
4 on.

5 So hopefully that will be one of the  
6 benefits that will accrue.

7 DR. BARR: All right. Thank you.

8 Those are very helpful comments. So what  
9 I'm hearing, I think, today is that FDA should  
10 continue to require the use of manufacturer's QC  
11 manual and check that folks have their initial  
12 training in modality, and that there is hopefully  
13 imminent information that will, although not today,  
14 soon allow us to write a specific set of regulations  
15 of the necessary elements for digital units.

16 DR. MARTIN: Can you clarify? I guess I'm  
17 asking for a time frame clarification. What will it  
18 entail? In other words, if this program were released  
19 from ACR and implemented arbitrarily January 2006,  
20 which it's not going to be ready, but say it's ready  
21 January 2006. What is the time frame for FDA then to  
22 adopt that so that the facilities are not caught in

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1 the requirement to have an ACR program and an FDA  
2 program?

3 Can you elaborate a little bit on how  
4 that's going to work?

5 DR. BARR: Yeah, I think Dr. Finder, who  
6 is our regulations expert can probably help with those  
7 time frames.

8 DR. FINDER: Now, is that January 1st?

9 (Laughter.)

10 DR. MARTIN: Fifteenth.

11 DR. FINDER: Fifteenth. Okay. Well,  
12 assuming it comes out on the 15th and it's not a  
13 weekend, there are two different aspects to it. One  
14 is the issue that Ms. Butler brought up about an  
15 alternative standard. They could submit something to  
16 us. We would review it as an alternative standard.  
17 Those usually go through within a matter of weeks or  
18 months in order to get those through the process.

19 And what that would allow, it would allow  
20 facilities to use that standard instead of what the  
21 manufacturer recommended. If you're talking about  
22 regulations such that this now would become the only

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1 de facto standard, then you're talking about going  
2 through I notice a common process that would probably  
3 go anywhere from 12 months to 18 months, probably more  
4 on the 18 months side, and would have to come before  
5 this committee and go through a formal process.

6 The alternative standard process can be  
7 done within the division because, as I had mentioned  
8 earlier in the morning session, we do have the  
9 ability, the authority to grant alternatives if those  
10 qualifications that I mentioned are met. And this  
11 might be one of those in which there were sufficient  
12 data to show that this would improve quality, speed  
13 things up, and could be approved through that process.

14 DR. BARR: Thank you.

15 For the physicists on the panel or Ms.  
16 Butler, anyone who wants to comment, do you feel that  
17 if we get to these tests that we feel are necessary,  
18 that the technology -- how do I say this -- will stay  
19 stable enough for a while that these will be, you  
20 know, implementable, or are we in such a flux right  
21 now that we're going to be looking at approving  
22 alternative standards or changing regulations

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1 constantly to accommodate digital?

2 DR. MARTIN: I think for all of us  
3 concerned we hope it's stable enough that whatever is  
4 developed would be adaptable to any of the new  
5 technologies that are coming on.

6 DR. BARR: Thank you.

7 DR. WILLIAMS: Yeah, I'd say there's  
8 probably no good way to predict what new technologies  
9 might arrive on the scene, but presumably this would  
10 be sort of a self-equilibrating thing. If there were  
11 a set of well established standards for performance,  
12 then in the FDA approval process for the instrument,  
13 then hopefully some of these things would get ironed  
14 out.

15 DR. BARR: And you think we could make  
16 this adaptable to the technology?

17 Penny, did you have?

18 MS. BUTLER: The group has been trying to  
19 write the tests general enough to accommodate the  
20 different technologies that are out there now, and  
21 there are going to have to be different specific  
22 procedures, which is going to be specific for each

1 manufacturer just because of the way the equipment  
2 works.

3 Be that as it may, currently working with  
4 the manufacturers and their own QC manuals, we've gone  
5 through numbers of different revisions of their QC  
6 manuals for the same model of equipment based on  
7 software and everything else.

8 So I think it would be worthwhile once we  
9 hit the regulatory stage to try to build in some  
10 creativity to allow for some changes as we go along.

11 Hopefully we'll learn more from the pilot testing  
12 that we're doing now and we can provide some advice as  
13 a result of that.

14 Maybe some of the manufacturers might have  
15 some input.

16 DR. BARR: Great. Thank you very much.

17 CHAIRPERSON HENDRICKS: Another comment  
18 from the audience. Please identify yourself.

19 DR. BARR: I was looking around for him.

20 DR. SANDRIK: John Sandrik, GE Health  
21 Care. We manufacture and sell medical equipment.

22 I think the idea that this will be stable

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1 is wishful thinking. I know certainly in our own  
2 equipment at least two developments that will affect  
3 QCs under PMA submissions right now. There's been  
4 presentations to this group. A couple of years ago  
5 Dr. Kopans was into the total synthesis systems.  
6 Certainly that's going to induce a lot of entirely new  
7 QC concerns, but essentially it's an outgrowth of a  
8 digital mammography system.

9 I guess he agrees.

10 (Laughter.)

11 DR. SANDRIK: But I know as Penny has  
12 mentioned -- we must have lost him. Should I continue  
13 or do we need to have a quorum in place?

14 Well, anyway, as Penny brought up, we've  
15 gone through several issues with our QC manual. We  
16 have software changes,. We have hardware changes, and  
17 we anticipate that those are going to continue.

18 I think one big difference between sort of  
19 the evolution of screen film and digital is that the  
20 mammography community had ten to 15 years of  
21 experience since green film before we even thought  
22 about setting down regulations for how it should be

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1 quality tested and evaluated.

2 You've had at most five years on one  
3 system and probably only one or two years on some of  
4 the other systems, and there's things you haven't even  
5 seen yet. So there's just not that kind of  
6 experience.

7 And I guess one thing, if I would add one  
8 plea here, you know, I think Dr. Barr had mentioned  
9 something before earlier. Having data before  
10 regulations. You know, I think I've looked at at  
11 least an outline of what the ACR has presented. We  
12 looked at what many of the manufacturers have, and I  
13 think there's a lot of consensus on what tests to do  
14 and there's probably even some consensus on what tests  
15 we're wasting our time on, but they're there because  
16 they're part of regulations or whatever.

17 But I think the big problem is setting  
18 what the action limits or the upper or lower bounds or  
19 whatever they are, the limits of acceptability. And  
20 that's a place where I have concern in terms of having  
21 the right data in order to make those limits relevant,  
22 and I know I have had some discussion with some of the

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1 DMIST participants on whether that data from the DMIST  
2 study could be used in QC development.

3 And at the time the response was that the  
4 study was never set up to do that. You know, so the  
5 ability to take some of that data and work it into QC  
6 limits may be something that still has to be worked  
7 out, but at least that could be some sort of source of  
8 information.

9 But I would really like to see some of the  
10 things like we were talking about with interpretive  
11 skills and all of the other applied to QC, that there  
12 be some sort of data to say, yes, sending it at this  
13 level really is going to make a difference between  
14 mammography quality, and it's not just a number pulled  
15 out of the air.

16 Thank you.

17 DR. BARR: Thank you.

18 For our transcriptionist purposes, I don't  
19 think this was ever said that DMIST is digital  
20 mammography imaging screening trial.

21 CHAIRPERSON HENDRICKS: Another comment  
22 from an audience member?

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1 MR. UZENOFF: My name is Bob Uzenoff, and  
2 I'm with Fuji Film Medical Systems, and we have a  
3 digital mammography system that's currently being  
4 reviewed in the FDA as a PMA.

5 And I would like to point out I think the  
6 wisdom in the original MQSA act of allowing for  
7 innovation and new technologies, the technology in our  
8 system which is under review is not the same exactly  
9 as devices that have been approved already. It was  
10 part of the DMIST trial, and so there is experience  
11 with that quality control program clinical experience,  
12 and I think the kinds of tests, as the previous  
13 speaker mentioned, we have an idea, I think a pretty  
14 good idea in physics of the types of things to look  
15 at, but just literally looking at the recommendation,  
16 they are a uniform set of quality tests and test  
17 criteria is a little strict.

18 Dr. Finder's recommendation of the  
19 alternative quality standards, I think, would nicely  
20 accommodate evolution in technologies and accommodate  
21 various technologies. In this X-ray realm, things are  
22 done differently, but it's not totally new. It's not

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1 like the difference between X-ray and MR.

2 We know about subject contrasts. We know  
3 things about resolution. We know about noise. We  
4 know what's important, but how to measure them and to  
5 set criteria, I think you'll find it's a little early  
6 to do that.

7 Thank you.

8 DR. BARR: Thank you.

9 DR. MARTIN: I was just going to reiterate  
10 the fact that, I mean, that's what Dr. Williams and I  
11 were saying with the ACR program. The ACR program  
12 will be pilot tested because, again, I agree complete  
13 with the speakers. We do not want to bring a program;  
14 we should not be implementing a program that has not  
15 been pilot tested to make sure it will work with all  
16 of the manufacturers, and that is the purpose. That's  
17 why that program is not out yet.

18 It's going to be tested before it's  
19 brought up.

20 DR. BARR: Thank you.

21 Well, I still think my idea of just  
22 flipping through this digital section was probably the

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1 best thing, but you all stopped me. So you know.

2 (Laughter.)

3 DR. BARR: Okay. Thank you for your  
4 comments.

5                   And now we get to our green and peach  
6       shading and specific regulations.   This is Section  
7       912.       Overall final assessment of findings are  
8       negative.   There were no recommendations to change  
9       that.   There was a recommendation to add the word  
10      "finding" or "findings" after "benign," also a  
11      negative assessment.

12                   Let's run through these and then we'll go  
13       back and see if anybody has any comments on each one.

14 I see probably benign recommendation to  
15 add "finding." Initial short-term follow-up suggested  
16 a finding or findings has a high probability of being  
17 benign.

18 Under recommendation for D was suspicious,  
19 to add "abnormality biopsy should be considered."

20 E, to add a biopsy should be considered  
21 after "highly suggestive of malignancy."

22 And new F, to add the wording "known

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1 biopsy proven malignancy, appropriate action should be  
2 taken. Reserve for lesions identified on the imaging  
3 study with biopsy proof of malignancy prior to  
4 definitive therapy."

5 Okay. B, adding the word "finding." I  
6 mean, unless -- is there major comment point anyone  
7 wants to make?

8 C, adding "finding," initial short-term  
9 follow-up suggested to the probably benign category.  
10 Any comment there?

11 D, under a suspicious, to add "abnormality  
12 biopsy should be considered." Anything there?

13 E, "highly suggestive of malignancy,  
14 biopsy should be considered." Any comment?

15 And then F, the known biopsy proven  
16 malignancy, and this says, "Reserved for lesions  
17 identified on the imaging study with biopsy proof of  
18 malignancy prior to definitive therapy." I guess I  
19 myself would wonder, you know, what about during  
20 definitive therapy. What about, you know, immediately  
21 following definitive therapy? Any comments on F?

22 Okay. In cases where no final assessment

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1 category can be assigned due to incomplete work-up,  
2 incomplete needs additional imaging valuation. The  
3 recommendation is to add "and/or prior mammograms for  
4 comparison."

5 "Show the assignment as assessment and  
6 reasons why no assessment can be made shall be stated  
7 by the interpreting physician, and a recommendation to  
8 add for cases rated zero because of need for prior  
9 examinations, reassessment must be performed within 30  
10 days to assigned category."

11 Any comments here?

12 MS. PURA: Dr. Barr, Linda Pura.

13 How come we don't just go right now the  
14 BI-RADS and use the BI-RADS as opposed to the various  
15 categories that are medically reported? I think the  
16 docs get very confused with they're reported in the  
17 BI-RADS. Why can we not just use the BI-RAD category  
18 one to zero to six instead of the alphabet?

19 I mean, it's not a major point, but I know  
20 a lot of our docs get very confused with those. It  
21 sounds very basic, but it's very true in practice.

22 DR. BARR: Well, maybe we should just get

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1 rid of BI-RADS and start over. How about that?

2 Charlie, do you want to comment?

3 DR. FINDER: Well, yeah. Let me go back  
4 to a little bit of history and kind of put some of  
5 this into perspective and where some of this is coming  
6 from.

7 The goal originally was to create a system  
8 so that the referring physicians would understand what  
9 the reports basically said. Before this requirement  
10 went into effect, reports could be long descriptions  
11 of things without any assessment whatsoever.

12 When we put into regulation the assessment  
13 categories, we basically picked the wording from the  
14 BI-RAD system. We basically used that. At that time,  
15 there was some discussion about using the numbers, and  
16 the feeling of the committee at that time was that the  
17 numbers themselves were not sufficient because then  
18 there would be confusion about what the numbers meant.

19 So what we did was we said you have to sue  
20 the language of the assessment categories. If you  
21 wanted, you could add a number with it, but the  
22 wording had to be there. And as I say, we basically

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1 took the wording from BI-RADS.

2 Now, over the course of years, things have  
3 -- we've learned. Let's put it that way, and not only  
4 we have learned, but BI-RADS have learned, and some of  
5 these have been modified to take that into account,  
6 not always with the best of results, and I'll give you  
7 one example in a minute.

8 But in addition to the language that was  
9 in the regulation for these assessment categories, we  
10 found that some facilities were using slightly  
11 different words, and what was happening was we finally  
12 had enough problems with that, enough facilities were  
13 being cited that we came up with a list of  
14 equivalence, and that's in our guidance, other wording  
15 that we would accept as equivalent to the assessment  
16 categories.

17 What is now happening is those lists are  
18 enlarging, and it's now getting to the point where you  
19 can pretty much write almost anything -- well, I  
20 shouldn't say that. It's not that bad, but it's  
21 getting confusing enough so that facilities are now  
22 having problems even understanding the BI-RAD system

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1 because the latest BI-RAD system now has broken down  
2 some of these categories even further, and you've now  
3 got things like low suspicion, moderate suspicion.  
4 It's getting more and more confusing.

5 One of the problems that we've done, and  
6 we've actually accepted the alternative standard for  
7 this one is the one that talks about the incomplete  
8 category where we've added and/or prior mammograms for  
9 comparison.

10 We've gotten feedback from some facilities  
11 and from some referring physicians that now they don't  
12 know what this means anymore because in the old days  
13 it would just be incomplete and need additional  
14 imaging evaluation.

15 With the current wording, now they don't  
16 know whether the patient needs additional imaging  
17 evaluation or they're waiting for a comparison. So in  
18 order to be helpful, in order to be flexible, we may  
19 have created a system that is even more confusing.

20 Another difference between our assessment  
21 categories and BI-RADS, as at least written here is we  
22 did not tie the assessment category to a

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1 recommendation. We gave the facilities flexibility to  
2 use an assessment category and supply a different  
3 recommendation if they believed that was indicated.

4 If we make this a regulatory change, then  
5 that won't be allowed. Okay? Some of these will now  
6 be tied to specific recommendations. So those are  
7 things to consider with this.

8 Another difference is that while IOM  
9 recommended that we add one of the approved  
10 alternative standard assessment categories, number F  
11 here or letter F here, they did not deal with one of  
12 the other ones that we had already approved, and that  
13 deals with marker placement during an interventional  
14 procedure. Why they didn't include that I'm not  
15 exactly sure.

16 And those were the comments that I wanted  
17 to make before you guys started discussing these  
18 suggested changes. So that's where we basically came  
19 from.

20 The whole idea of this is to make it as  
21 clear as possible to the referring physician what the  
22 interpreting physician thought of this mammogram and

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1 what should be done next.

2 DR. BARR: And I really wasn't being flip  
3 when I said maybe we should ditch BI-RADS and start  
4 over. I was trying to get to what Dr. Finder was  
5 saying, which was the original intent. I think we've  
6 come full circle now, and maybe the radiologist  
7 speaking his or her intent into the dictation of what  
8 should be done with this patient and the results of  
9 the mammogram is a viable alternative to keeping  
10 adding onto categories and allowing more variations of  
11 words, et cetera, et cetera.

12 So I'd like to hear your comments.

13 DR. FINDER: One other issue that has come  
14 up is that the assessment categories here basically  
15 are an assessment or some kind of graduation or  
16 quantification of malignant status, how malignant you  
17 think this mammogram represents.

18 We have had a case that's been brought to  
19 our attention where a ruptured implant got an  
20 assessment category of negative because there was no  
21 evidence of malignancy, no suspicion of malignancy,  
22 and that is cases going to the courts now because they

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1 got a negative assessment with a ruptured implant, and  
2 they're bringing that as an issue.

3 So I think there's some confusion as to  
4 what the purpose of these assessment categories are  
5 supposed to be, whether they only refer to malignancy,  
6 whether they refer to even benign conditions of the  
7 breast.

8 We've always had complaints or comments  
9 about these assessment categories don't necessarily  
10 fit male breast mammograms, and that it's not  
11 appropriate for that.

12 So I just want to hear your comments, your  
13 thoughts. Should we be looking at a new assessment  
14 category or should we try and define the old one?

15 I would also state that most of the  
16 facilities, the vast majority of the facilities are  
17 familiar with this, and to change this would be a huge  
18 change in the way mammography facilities practice. So  
19 we have to be very, very careful before we suggest  
20 anything.

21 I also see a hand going up, and I can  
22 answer this question. Any change that we made in

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1 these assessment categories would cause a huge change  
2 in software companies that have to redo all of their  
3 programs.

4 DR. BARR: From the audience.

5 MS. MYERS: Susanne Myers, again, with  
6 Mammologics.

7 One thing I just want to point out when  
8 you're looking at these. A lot of facilities -- and I  
9 think Dr. Finder was alluding to that -- they tie  
10 their patient notification letter messages to these  
11 categories, and so if you make any changes to that,  
12 it's going to be a challenge for the facilities to get  
13 the correct letters to the patients. That could even  
14 cause more confusion.

15 So just something to consider.

16 DR. BARR: Thank you.

17 Yes, additional comments from the  
18 audience?

19 MS. BUTLER: Penny Butler from ACR.

20 If could move to the previous slide.

21 DR. BARR: Sure. Maybe. I don't know.

22 (Laughter.)

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1 DR. BARR: Charlie, can you help me?

2 MS. BUTLER: I just wanted to point out  
3 that number E there, which is BI-RADS Category 5, I  
4 believe the BI-RADS describes "appropriate action  
5 should be taken," not "biopsy should be considered."

6 DR. BARR: Yeah. But do you think that  
7 this is the IOM recommendation, or do you think we  
8 have the IOM recommendation wrong?

9 MS. BUTLER: I don't know. I would have  
10 to look at my IOM book.

11 DR. BARR: Yeah, I didn't know if you were  
12 intimately involved in that.

13 CHAIRPERSON HENDRICKS: Additional comment  
14 from the audience?

15 DR. BASSETT: I think that the BI-RADS has  
16 become not only national standard, but an  
17 international standard. Most of the countries that  
18 have developed accreditation programs have developed  
19 and incorporated this into their programs. It works,  
20 and I think it's a mistake to change it.

21 When you give someone an F for what's  
22 really a five, basically you don't have to tell the

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1 surgeon what to do. They may have different options  
2 they want to take. They may want to take the patient  
3 directly to surgery in certain circumstances,  
4 depending on the clinical factors and so on, and  
5 that's why it was called "appropriate action should be  
6 taken."

7 And actually that's used for F, but it  
8 should also be for E, highly suggestive of malignancy.

9 DR. BARR: Yeah, I think that's what Penny  
10 has.

11 DR. BASSETT: Almost 100 percent sure, and  
12 again, I'd emphasize what was spoken before, that many  
13 facilities have tied their auditing and so on to these  
14 numbers, and they've got it in their software and so  
15 on. And we're trying to encourage them to do audits,  
16 and yet we're going to make it even harder for them  
17 because all of their previous studies are identified  
18 by the numbering system.

19 DR. BARR: Would you have a recommendation  
20 for the one that said to put in "and/or prior  
21 mammograms," "additional imaging and/or prior  
22 mammograms"? Because clinicians have told us they

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1 don't know what they're supposed to do. Does that  
2 mean the radiology department is taking care of it?  
3 Does that mean they have to do something?

4 DR. BASSETT: No, it's a very difficult  
5 issue. It has to be clear that what you're asking for  
6 is old films versus more imaging. For several reasons  
7 it should be identified that way.

8 One is that you want to keep track of  
9 them. So our quality assurance person would have to  
10 know which were old films because she would be  
11 pursuing those until they are found or let us know if  
12 she couldn't get them within a certain time.

13 And the ones with additional imaging are  
14 actually going to count as call-backs in your medical  
15 audit. The old films really don't need to be call-  
16 backs.

17 DR. BARR: Would you have a comment on the  
18 rated zero, giving a time frame for the zero rating?  
19 I think I have it up on the screen now for cases rated  
20 zero. A time frame for changing the assessment.

21 DR. BASSETT: Oh, I think that's a goal to  
22 go for certainly in terms of if you can contact the

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1 patient and find the patient and so on to get them  
2 back.

3 I think that's not inappropriate, and  
4 justify if you can't do it.

5 DR. BARR: Thank you.

6 DR. MONTICCILOLO: I agree with Dr. Bassett  
7 that that is a goal, the 30 days, but to make it must  
8 be performed in 30 days, I mean, we have patients who  
9 think that if they get their mammogram right before  
10 they go on vacation, somehow they'll be saved from  
11 anything bad because, after all, everyone knows  
12 they're going on vacation.

13 And so we have this continual problem with  
14 little ladies who are going off for a month or two and  
15 have their mammogram right before, and then we try to  
16 get them back, and they say, "But can't I come six  
17 weeks from now?" or whatever.

18 And so we have a hard time trying to track  
19 them and get them to comply with the regulations when  
20 they aren't aware of them. So I think it's a good  
21 idea to say, gee, every effort should be made, but to  
22 make it mandatory that it be done within 30 days, I

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1 think it sometimes is difficult.

2 I mean, we call them back right away, but  
3 there are just some patients that won't comply with  
4 it.

5 DR. FINDER: It's Dr. Finder.

6 I just want to clarify one thing. The way  
7 this is written, the recommendation, it's only those  
8 in which you're waiting for comparison films, not in  
9 which you're asking for additional studies that would  
10 have to be redone in 30 days.

11 So it's only --

12 DR. MONTICCILOLO: Well, that's even a  
13 bigger problem for us, getting a facility to send an  
14 old film. We have to put a tremendous amount of  
15 resources into that. First of all, we often send  
16 letters, faxes, calls, and if it's outside our general  
17 area, it takes weeks and weeks to get these films. We  
18 have films show up six weeks later all the time. So  
19 the question is what to do with those.

20 DR. FINDER: Well, that is the point  
21 because the impetus for this recommendation from IOM  
22 is the situation where somebody reads a mammogram as

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1 incomplete, needs comparison films, and send out that  
2 report.

3 And right now under the current  
4 regulations, there is no requirement that a, quote,  
5 unquote, final assessment category go out at some  
6 point in the future. This is an attempt to require  
7 that that happen. So if you don't get those  
8 comparison films, you will reassess those films and  
9 give an assessment based on what you have at that  
10 point.

11 And they are saying 30 days. Is that a  
12 reasonable time frame? Isn't it? But it's to address  
13 that issue and to prevent people from sending out  
14 incomplete studies and never getting the comparison  
15 films and never giving a final report, in effect.

16 So that's the issue that's really being  
17 addressed here.

18 DR. FERGUSON: Don't we already have a 30-  
19 day requirement?

20 DR. FINDER: The requirement is that a  
21 report has to go out in 30 days, but if that report is  
22 a zero, an incomplete, that has met the requirement.

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1 So that it is possible for somebody to send out that  
2 report and then never get the old films and never have  
3 a final report go out.

4 So that was their attempt to address in  
5 regulation that issue.

6 DR. BARR: So -- go ahead.

7 DR. FERGUSON: I was going to say I guess  
8 I was under the wrong assumption that you had to do  
9 something in 30 days. So what we do at 30 days if we  
10 don't have the films, we send out a report, and I  
11 guess that you're wanting to mandate that that be  
12 done. I thought it already was. I guess I was --

13 DR. BARR: This is an IOM recommendation,  
14 and if we keep BI-RADS because it's standard and  
15 because it's attached to patient notification, so in B  
16 do we accept a recommendation of adding a word  
17 "finding" because somebody thinks it should be added?

18 Do we keep giving alternative wording?  
19 And how do we --

20 DR. FERGUSON: I think we leave the words  
21 alone. I think that we're pretty standard, and that's  
22 what we've looked for for a long time is

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1 standardization. I think it's everything we've talked  
2 about. So I'd say leave it alone.

3 CHAIRPERSON HENDRICKS: Another question  
4 from the audience?

5 DR. LEE: I have a comment. Carol Lee  
6 from ACR.

7 I agree with what Ms. Pura said. I want  
8 to emphasize how our clinicians now having been living  
9 with BI-RADS for the length of time that it has been  
10 in existence now have a really good understanding of  
11 what the numbers mean, and to change at this point, I  
12 think, would introduce a lot of unnecessary confusion  
13 into an already confusing area.

14 The other comment I wanted to make is that  
15 the BI-RADS committee of the American College of  
16 Radiology has devoted an incredible amount of time and  
17 energy in developing the wording, and lots of effort  
18 by experts has gone into this, and I would urge FDA in  
19 their regulations to keep the same terminology as BI-  
20 RADS so that we're all talking one language.

21 Thanks.

22 DR. MONTICCILOLO: Carol, can I ask you a

1 question?

2 DR. LEE: Sure.

3 DR. MONTICCILOLO: This is going to add  
4 something that's not in this, but I just want to ask  
5 since you're familiar with the BI-RADS committee, what  
6 about the patient who has a palpable abnormality but  
7 no mammographic findings? Because in my --

8 DR. LEE: This is something that confuses  
9 clinicians terribly.

10 DR. MONTICCILOLO: Absolutely, and my  
11 understanding, and actually Dr. Bassett is a  
12 longstanding member of the BI-RADS committee; my  
13 understanding is that the committee is addressing that  
14 question and others, for example, the implant, you  
15 know, the cases that are not suspicious for  
16 malignancy, but have other findings.

17 And the BI-RADS committee is not a one  
18 shot thing. It meets on a regular basis, and it is  
19 addressing these issues that come up, and that's why I  
20 would urge that that language in BI-RADS be adopted.

21 DR. BASSETT: That's another issue that --

22 CHAIRPERSON HENDRICKS: Please reintroduce

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1 yourself every time you come to the microphone.

2 DR. BASSETT: Larry Bassett representing  
3 Society of Breast Imaging.

4 CHAIRPERSON HENDRICKS: Thank you.

5 DR. BASSETT: One other reason that you  
6 might want to not jump into that area is because it  
7 has now been extended to ultrasound and MR in a way  
8 that whenever possible it is kept the same. Like if a  
9 mass is round on mammography, ultrasound and MR, it  
10 will have that same terminology.

11 So when you start messing with the  
12 mammography when you're also going to affect the  
13 ultrasound and the MR, which were developed by people  
14 who spent a long time getting consensus because  
15 everybody was doing it differently, and the same for  
16 ultrasound. They now have the standardized  
17 terminology, and that's another big step forward.

18 So this is not just related to  
19 mammography. It's every imaging modality in breast  
20 imaging, and it was made to be flexible. So if there  
21 is a reasonable reason to change it, the committee  
22 will change it. They just need the input.

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1                   And it has changed over the years. For  
2                   example, Category F, which we call Category 6.  
3                   Category 6 was added because so many patients are  
4                   getting induction chemotherapy prior to having their  
5                   definitive treatment with surgery, and those patients  
6                   need to be evaluated with imaging a lot of times, and  
7                   so to give them a four or five would be appropriate.  
8                   So we give them a six, and that's where that came  
9                   from.

10                   So that's another one that will be in all  
11                   three types of modalities.

12                   So I think it's a mistake to change  
13                   something that has taken so long to develop, and it  
14                   has finally gotten national approval. It is flexible  
15                   though, and it can change for those ways.

16                   For example, Category 4, which is  
17                   suspicious, there's an option now to make it 4(a), (b)  
18                   or (c) because it's such a wide category. So if it's  
19                   just slightly suspicious, most likely a fibroid  
20                   (unintelligible) cyst, why not do a cyst aspiration?  
21                   That's a 4(a).

22                   And then if it's just intermediate in its

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1 suspicion, it would be a (b). And if it's higher  
2 suspicion like 50 percent and above, then it would be  
3 a (c), and then five is restricted for those that  
4 you'd bet your house on it basically.

5 CHAIRPERSON HENDRICKS: Does the committee  
6 right now perceive that there's a problem with the  
7 Category 0, recognizing the two separate sets of  
8 patients.

9 DR. BASSETT: They've had a lot of comment  
10 and work on Category 0, absolutely, and they're  
11 working that out, but they're trying to get some  
12 consensus and input from all the other societies as  
13 well, not just radiology, but surgery and so on. So  
14 it's a difficult process.

15 But you can subcategorize zero into zero-  
16 zero if you want to do that here for old films, zero  
17 old for old films and zero (a) for additional imaging,  
18 too. That's another option that you can use.

19 CHAIRPERSON HENDRICKS: I see. Thank you.

20 DR. BARR: Thank you very much.

21 I just wanted to show the rationale for  
22 these recommendations BI-RADS categories to minimize

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1 confusion between interpreting physicians and other  
2 clinicians, and that FDA has already approved the new  
3 Category F in an alternative standard.

4 Thank you. Those are helpful comments.

5 D is the establish luminance standards for  
6 viewing mammograms and the proposed wording to the  
7 appropriate regulatory section is viewboxes used for  
8 interpreting mammograms and clinical image quality  
9 reviewed by the technologist should be capable of  
10 producing the luminance of at least 3,000 candela per  
11 square meter. The illumination levels must be less  
12 than or equal to 21 lux.

13 The committee says that evaluation of  
14 viewboxes during inspection is not recommended. The  
15 rationale is viewing conditions are critical to detect  
16 subtle contrast differences, and that the 1999 ACR  
17 quality control manual has suggested standards.

18 The one comment I would make is the  
19 standard comment I have on dealing with regulations,  
20 is it's important enough to put in a regulation, but  
21 it's not important enough to have an enforcement tool  
22 for it, and that's always a problem when you recommend

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1 putting something in regulation and then there's no  
2 way to enforce it. The recommendation, the evaluation  
3 is not recommended during inspection. So it's a  
4 regulation that we can't enforce if we don't have a  
5 compensatory inspection or enforcement component.

6 DR. MARTIN: Melissa Martin.

7 I'm confused when you say there's no  
8 inspection because the physicists do this. As far as  
9 those of us who are inspecting ACR accredited  
10 facilities, I guess I would highly recommend that this  
11 be approved because we're making this measurement on  
12 an annual basis as part of our annual physics report  
13 already.

14 DR. BARR: Right, but it's not part of the  
15 inspection procedure, and IOM doesn't think that it  
16 should be.

17 DR. MARTIN: I beg to disagree with IOM.

18 DR. BARR: Thank you.

19 Any comments on this standard?

20 CHAIRPERSON HENDRICKS: From the audience.

21 MR. MOURAD: Wally Mourad, FDA.

22 It's true that it's not in the inspection

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1 procedures, but if it's in a physicist report and if  
2 the physicist says it's wrong, fix it, the facility  
3 has to fix it. So in a way it's inspected.

4 DR. MARTIN: Well, it's inspected and it's  
5 part of the physicist report for those that are ACR  
6 accredited, but again, it is a measurement we are  
7 making. We can recommend, but it would be a lot more  
8 forceful if it were part that they had to fix it  
9 because right now it's only a recommendation. That is  
10 true. They do not have to fix it.

11 We can tell them all day, but there's no  
12 teeth to it.

13 DR. BARR: Exactly. Thank you.

14 From the audience?

15 MS. BUTLER: Penny Butler with the ACR.

16 One thing that AB's accreditation bodies  
17 look for during the three-year accreditation is that  
18 we get a copy of the physicist report. If the  
19 physicist says that a certain regulation is not met,  
20 we will not accredit them until we get something back  
21 from the facility saying that they have corrected the  
22 problem. So in that sense it is in force when they go

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1 through accreditation.

2 CHAIRPERSON HENDRICKS: What is your take  
3 on this recommendation that the viewboxes not be  
4 evaluated? I'm just having a little trouble  
5 understanding the background for this IOM  
6 recommendation that the viewboxes not be inspected.

7 MS. BUTLER: Not be evaluated during  
8 annual MQSA inspection. I agree with that, and I  
9 agree with that because it would be checked during the  
10 medical physicist annual survey, and so there would be  
11 a measurement to determine if it does meet  
12 requirements. There would be oversight by the  
13 accrediting body to make sure that it meets MQSA  
14 requirements.

15 CHAIRPERSON HENDRICKS: You feel their  
16 intent might be that it was a duplication of something  
17 that's already in place?

18 MS. BUTLER: Yes.

19 CHAIRPERSON HENDRICKS: I see. Is that  
20 also your understanding, Dr. Barr?

21 DR. BARR: I'm interested in knowing how  
22 it can go from what Ms. Martin says, which is a

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1 recommendation by the physicist that if this doesn't  
2 meet, that it be fixed to something that, you know, if  
3 it's that important, it needs teeth.

4 So I'm a little confused about the  
5 recommendation.

6 DR. MONTICCIOLO: I think the issue here  
7 is time during inspection because this would take  
8 extra time in the inspection, and as Penny Butler  
9 pointed out, it already is required to be fixed by the  
10 accrediting bodies and so there is some teeth in it,  
11 and I know that to be the case because sites that I  
12 have checked when they had this problem, the ACR's  
13 hand in it forced it to be fixed, based on the  
14 physicist report.

15 DR. BARR: And that's an every three year  
16 process, the accreditation. I just wanted to point  
17 that out.

18 Thank you.

19 DR. MARTIN: I would reiterate I'm not in  
20 any way saying that this should be done by the MQSA  
21 inspector during their annual inspection. It is  
22 something to be handled by the physicist. I would

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1 just recommend that, you know, if necessary, this body  
2 recommends that FDA adopt that as a standard, but I'm  
3 not endorsing at all that it be part of the MQSA  
4 inspector's task. This is a physicist task.

5 DR. BARR: Thank you.

6 DR. FINDER: Yes. Dr. Finder.

7 I just wanted to kind of go back and give  
8 some history about this issue because when the final  
9 regulations were being worked on, the issue about  
10 luminance standards for viewboxes was discussed. In  
11 fact, viewing conditions in general were discussed.  
12 It was decided at that point not to mandate high  
13 luminance viewboxes for mammography.

14 Instead, what the recommendation from the  
15 committee was is to use or require hot lights to be  
16 available which can produce these levels of luminance  
17 without having the more expensive viewboxes.

18 There was an issue about masking, and that  
19 I think is an issue that should also be considered if  
20 you're going to talk about the viewboxes because some  
21 testimony we got was that if you don't mask  
22 appropriately on these higher luminance viewboxes, it

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1 can actually worsen your visualization of the image  
2 because you're getting all of this extraneous light  
3 hitting your eye.

4 So I wouldn't necessarily just limit it to  
5 the viewbox. You might want to also consider viewing  
6 conditions. I will tell you at the last time this was  
7 discussed we got into the issue about practice of  
8 medicine, and people at that committee were hesitant  
9 to go too deeply into this. In fact, the  
10 recommendation from the committee was not that we  
11 require that masking be used; just that the facilities  
12 have masking available.

13 So a lot of these issues probably go into  
14 this one thing. I guess the question is do we look at  
15 viewing conditions in general and come up with some  
16 specifications for the entire range, including use of  
17 masking, use of certain types of viewboxes,  
18 illumination levels in the room itself which are  
19 mentioned in this requirement that they suggest.

20 So what do people think? How far should  
21 we go on this and is this an area that we should be  
22 getting into again?

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1 DR. WILLIAMS: Don't we already have  
2 recommendations in ACR guidelines for two out of those  
3 four things that you mentioned for the background  
4 light that's hitting the monitors? So the illuminance  
5 and the luminance of the monitors themselves.

6 As far as masking goes, probably for soft  
7 copy viewing it may not be quite as much of an issue  
8 since you don't have the bright borders to worry  
9 about, and I forget what the fourth one was.

10 DR. MARTIN: No, they're all in the ACR.  
11 Basically the question, if I understand it, Dr.  
12 Finder, you're wanting us to -- are you wanting to  
13 know if the committee wants to recommend that MQSA or  
14 that we recommend the adoption of what's in basically  
15 Test 11, the viewing conditions for the ACR manual at  
16 this time?

17 Because all of those items are covered.

18 DR. BARR: Right, and I think that's the  
19 question, is this something -- are viewing conditions,  
20 including the luminance and lots of other things  
21 related to viewing conditions, something that we want  
22 to be into and regulating?

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1 DR. FINDER: Right. Another issue to keep  
2 in mind that have been previously brought up before,  
3 that over the years the optical density of the films  
4 has increased so that there are darker films. So that  
5 increased luminescence or illuminant viewboxes might  
6 make more sense now than they would have, let's say,  
7 five or ten years ago when we were talking about some  
8 of the initial regulations.

9 So, again, just we want to hear your  
10 opinion on whether we should go ahead with further  
11 regulation of viewing conditions.

12 DR. BARR: And if we put in regulations  
13 that you have to mask, how do we enforce that? You  
14 know, does the inspector watch the radiologist read?

15 I mean, you have to think of when we do  
16 these things how do we go about making sure that  
17 they're done, or do we?

18 DR. FINDER: And I would also add to that  
19 the issue of does anybody have any idea about how many  
20 viewboxes would not meet these conditions and how many  
21 facilities would have to get new viewboxes and whether  
22 you could achieve the same result using a hot light

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1 versus this.

2 MS. RINELLA: Let me just add, I'm Diane  
3 Rinella, a mammography consultant.

4 I travel throughout the United States.  
5 I've been all across this country, and the majority of  
6 the places that I do work at, I'm working with them on  
7 actual patients and viewing films on their viewboxes  
8 that they're using for their criteria image critique.

9 And the majority of these viewboxes when I  
10 ask the technologist are these the same luminance as  
11 your radiologists, they look at me with a blank face.  
12 They have no clue. They do not have hot lights.  
13 They don't have masking, and their overhead lights  
14 are on, and they don't know really that these are not  
15 the way to do films.

16 So I'm glad you brought this up.

17 DR. FINDER: Are these the techs or the  
18 interpreting physician viewboxes?

19 MS. RINELLA: These are the technologist's  
20 viewboxes that should have basically the same  
21 luminance as the radiologist reading the film.

22 DR. FINDER: Okay, because the regulations

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